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Patent Docket P0998D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Jeffrey L. Cleland et al. Serial No.: 09/273,230 Filed: March 18, 1999 For: PROTEIN FORMULATION	Group Art Unit: 1642 Examiner: Christopher Yaen Confirmation No: 6833 CUSTOMER NO: 09157 Express Mail No. EV 384 511 070 US November <u>22</u> , 2006 <u>Anna Kan</u> Anna Kan
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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of

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allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449.

Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR §1.98(a)(2)(ii)]. See Final Rule 1287 OG (October 12, 2004). Other documents cited with an asterisk have not been supplied because they were previously cited by or submitted to the Office in prior application Serial No. 08/615,369, filed March 14, 1996 and benefit from the prior application is claimed in this application under 35 U.S.C §120. However, copies of any cited document will be

provided in its entirety at the request of the Office.

BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

not given
 given for each listed item
 given for only non-English language listed item(s) [Required]
Item 337 has an English translation attached.
 in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

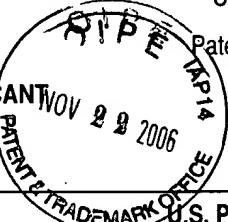
Respectfully submitted,

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Date: November 21, 2006

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P0998D1	Serial No. 09/273,230
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Cleland et al.	
				Filing Date 18 Mar 1999	Group 1643

U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	*319	2003/0202972	30.10.03	Andya et al.			
	*320	2004/0197326A1	07.10.04	Fick et al.			
	*321	2006/0099201 A1	11.05.06	Andya et al.			
	*322	4,165,370	21.08.79	Coval, M.			
	*323	4,371,520	01.02.83	Uemura et al.			
	*324	4,439,421	27.03.84	Hooper et al.			
	*325	4,482,483	13.11.84	Curry et al.			
	*326	4,515,776	07.05.85	Taniguchi et al.			
	*327	4,835,257	30.05.89	Friedrich-Fiechtel et al.			
	*328	5,449,760	12.09.95	Chang			
	*329	5,543,144	06.08.96	Chang, T.			
	*330	5,614,611	25.03.97	Chang, T.			
	*331	5,945,098	31.08.99	Sarno et al.			
	*332	6,037,453	14.03.00	Jardieu et al.			
	*333	6,329,509	11.12.01	Jardieu et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	334	073,371	09.03.83	EPO				
	335	196,761	08.10.86	EPO				
	336	407,392	28.10.98	EPO				
	337	61-194035	28.08.86	JAPAN (ENGLISH TRANSLATION ATTACHED)				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

338	Andya et al., "Mechanisms of aggregate formation and carbohydrate excipient stabilization of lyophilized humanized monoclonal antibody formulations" <i>AAPS PharmSci</i> (Article 10 (http://www.pharmsci.org)) 5(2):94-104 (2003)
339	Berglund et al., "Spirometric studies in normal subjects" <i>Acta. Med. Scand.</i> 173:185-192 (1963)
340	Boulianne et al., "Production of functional chimaeric mouse/human antibody" <i>Nature</i> 312:643-646 (December 13, 1984)
341	Carpenter et al., "Separation of freezing- and drying-induced denaturation of lyophilized proteins using stress-specific stabilization. I. Enzyme activity and calorimetric studies" <i>Archives of Biochemistry & Biophysics</i> 303(2):456-464 (Jun 1993)
342	Cleland et al., "A specific molar ratio of stabilizer to protein is required for storage stability of a lyophilized monoclonal antibody" <i>Journal of Pharmaceutical Sciences</i> 90(3):310-321 (Mar 2001)
343	Fisher et al., "Biostatistics: a methodology for the health sciences", New York:John Wiley & Sons pps. 861-862 (1993)
344	Gammimune Package Insert

Examiner	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P0998D1	Serial No. 09/273, 230
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		Applicant Cleland et al.		
		Filing Date 18 Mar 1999	Group 1643	
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)				
345	Gammagard Package Insert			
346	Gammar Package Insert			
347	Gerber, D., "Copper-catalyzed thermal aggregation of human gamma-globulin. Inhibition by histidine, gold thiomalate, and penicillamine" <u>Arthritis and Rheumatism</u> 17(1):85-91 (Jan-Feb 1974)			
348	Lazar et al., "Transforming Growth Factor α : Mutation of Aspartic Acid 47 and Leucine 48 Results in Different Biological Activities" <u>Molecular & Cellular Biology</u> 8(3):1247-1252 (Mar. 1988)			
349	Prestrelski et al., "Separation of freezing- and drying-induced denaturation of lyophilized proteins using stress-specific stabilization. II. Structural studies using infrared spectroscopy" <u>Archives of Biochemistry & Biophysics</u> 303(2):465-473 (Jun 1993)			
350	Roberts et al., "An integrated strategy for structural characterization of the protein and carbohydrate components of monoclonal antibodies: application to anti-respiratory syncytial virus MAb" <u>Analytical Chemistry</u> 67(20):3613-3625 (Oct 15, 1995)			
351	Townsend and DeLuca, "Nature of aggregates formed during storage of freeze-dried ribonuclease A" <u>Journal of Pharmaceutical Sciences</u> 80(1):63-66 (Jan 1991)			
352	Townsend and DeLuca, "Use of lyoprotectants in the freeze-drying of a model protein, ribonuclease A" <u>Journal of Parenteral Science & Technology</u> 42(6):190-199 (Nov-Dec 1988)			
Examiner		Date Considered		
<small>*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>				